

### **REMARKS**

The present Amendment is in response to the Office Action mailed March 3, 2010. 1-4, 6-17, and 19-20 remain pending in view of the above amendments. Applicants note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. Applicants also note that the remarks presented herein have been made merely to clarify the claimed embodiments from elements purported by the Examiner to be taught by the cited reference. Such remarks, or a lack of remarks, are not intended to constitute, and should not be construed as, an acquiescence, on the part of the Applicants: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in this case. Applicants reserve the right to challenge the purported teaching and prior art status of the cited references at any appropriate time. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference,

### **PRIOR ART REJECTIONS**

#### **Rejection Under 35 U.S.C. §102**

The Office Action rejected claims 1-4, 6-17, 19-21 and 24-30 under 35 U.S.C. § 102(e)<sup>1</sup> as being anticipated by U.S. Patent No. 7,334,379 (*Siegel*). Because *Siegel* does not teach or suggest each and every element of the rejected claims, Applicants respectfully traverse this rejection in view of the following remarks.

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<sup>1</sup> Because *Siegel* is only citable under 35 U.S.C. § 102(e) Applicants do not admit that *Siegel* is in fact prior art to the claimed invention but reserve the right to swear behind *Siegel* if necessary to remove it as a reference.

Claim 1 recites a method *"of automatically filing tablets into tablet containers . . . wherein upon receiving the patient order, a plausibility check of the prescription data regarding the possible overdosage and the mutual compatibility between tablet type is carried out and, in case an overdosage or an incompatibility is detected, the patient order is rejected."*

The application discloses in ¶[0019] that *"For the benefit of the patient, a plausibility check of the prescription data regarding a possible overdosage and the mutual compatibility between tablet types is suitably carried out already upon receiving the patient order and, in case an overdosage or an incompatibility is detected, the patient order is rejected."*

Furthermore the application discloses in ¶[0033] that: *"It should be mentioned that the data specific to the patient order (medicament, number etc.) can be subjected to a plausibility check regarding mutual compatibility, overdosage, contraindications, with such a plausibility check suitably already being integral with the reception means 30."*

The reception means in claim 11 receives a patient order, which includes prescription data and the patient identification. The reception means performs a plausibility check where data specific to the patient order (medicament, number, etc.) are checked with regard to mutual compatibility, overdosage or contraindications of these prescriptions (see ¶[0019; 0033]). Based on the disclosure in the application, one skilled in the art understands that such a plausibility check may include checking whether a medicament based on the prescription information of this medicament is compatible with another medicament on the prescription data.

For example, the prescription data of a medicament may indicate that this medicament should not be taken if pregnant, while the prescription information of another medicament listed in the prescription data for the same patient is particular for pregnant women. The plausibility check in this example would result in a rejection of this patient order.

Another example for a plausibility check would be a plausibility check of overdosage where the prescription data (e.g., based on a typo) lists a dosage of ten tablets of the medicament per day while the prescription data of that medicament indicates two tablets per day as the maximum dosage for a grown up person. Again, the plausibility check would result in a rejection of this patient order.

Having passed this plausibility check upon receiving the patient order or at the reception means, the tablet filling system processes the patient orders not rejected during the plausibility check. After filling a support facility 10 (tablet compartments of a tablet container) with the tablets according to the patient order, a check of completeness and correctness is performed at a subsequent control station 60 (see ¶[0032]). In addition, the prescription data and patient identification are printed on a printable field on the pseudo-blister 10 and in addition stored in an information carrier 11 to enable the operator to control the content of the pseudo-blister 10 during and after the filling process (see ¶[0033]).

The application therefore discloses a tablet filling system with a plausibility check upon receiving the patient order upfront filling the pseudo-blisters and checks during and after having filled the pseudo-blisters with the tablets. Amended claims 1 and 11 claim a tablet filling system and method with a plausibility check upon receiving the patient order.

The Examiner in the Office Action refers to *Siegel* and states that claims 1 and 11 are anticipated by the disclosed method and system of filling containers. With regard to a plausibility check, the Examiner refers to column 1, lines 45-47 of *Siegel* where it is stated: *"Managed care facilities now use patient-specific packaging that provide all of the designated-patient's prescription drug needs for a given period of time. The period of time is typically a one week or one month supply."*

To understand the meaning of "managed care," *Siegel* states in column 1, line 39-44 that *"However, it has been recognized that for managed care and other settings, there is a significant need for automated pharmaceutical packaging machines which are capable of selectively positioning one or more pharmaceutical doses into each of a plurality of individual cavities in an overall pharmaceutical product package"*. Neither the disclosure referred to by the Examiner nor the term "managed care" discloses

anything about a plausibility check of a tablet filling system and method upon receiving the patient order.

More specifically, this section of *Siegel* simply refers to managed care in the sense of automated packaging machines capable of selectively positioning one or more pharmaceutical doses into each of a plurality of individual cavities in a product package. Automatically positioning pharmaceutical doses into cavities does not disclose the plausibility check in claims 1 and 11. Positioning doses into cavities does not check the prescription data regarding a possible overdosage or the mutual compatibility between tablet types. Claims 1 and 11 therefore are patentable over *Siegel*. In particular, *Siegel* fails to disclose each and every element of the pending claims as the elements are arranged in the claims.

The Examiner in the Office Action furthermore refers to *Williams* and in particular to column 4, lines 4-7 to disclose such a tablet filling system and method with a plausibility check upon receiving the patient order. Applicants do not see any relevance of *Williams'* disclosure at column 4, lines 4-7. This portion of *Williams* states that the method of *Williams* comprises using a computer to control the robotic arm during movement of the bulk container and pill bottle. Using a robotic arm as disclosed in *Williams* fails to disclose a plausibility check as recited in claim 1.

However, *Williams* at column 4, lines 10-14 discloses "*The method of the present invention further comprises the step of moving the pill bottle to a conveyor after it has been filled so that the pharmacist can check the prescription and cap the bottle.*" *Williams* therefore discloses a manual check by the pharmacist after the bottles have been filled with the tablets, but does not disclose or provide any hint for an automated plausibility check of the prescription data upon receiving the patient order. Further, there is no disclosure that the manual check includes both a check regarding a possible overdosage and mutual compatibility between tablet types. Claims 1 and 11 therefore are new and patentable over *Williams* and *Siegel* and any combination of the disclosures of these prior art documents.

To conclude, prior art documents only provide disclosure about a check after the tablets have been filled into tablet containers and with this check only the number and type of tablets are checked whether they are in line with the prescription data. Claims 1

and 11, in contrast to these teachings, claim a plausibility check upon receiving the patient order. Only with the claimed plausibility check can it be ensured that possible overdosage and incompatibility of medicines (errors within the prescription order) with severe consequences for patients are avoided. Because the plausibility check is performed upon receiving the patient order, filling pseudo-blisters with wrong patient orders is avoided. This saves cost and time in case the wrong filled tablet containers are identified at all.

### **Rejection Under 35 U.S.C. § 103**

The Office Action rejected claims 22 and 23 under 35 U.S.C. § 103(a) as being unpatentable over *Siegel* in view of U.S. Patent No. 6,449,921 (*Kim*). Because claims 11 is patentable for the reasons discussed herein and because *Kim* does not remedy the deficiencies of *Siegel*, claims 22 and 23 are patentable over the cited art.

**CONCLUSION**

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney. In view of the recent USPTO initiative regarding compact prosecution, Applicant respectfully invites the Examiner to contact the undersigned at his earliest convenience in the instance that additional impediment exists to the prompt allowance of this case.

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Respectfully submitted,

/Carl T. Reed/ Reg. # 45454  
CARL T. REED

Registration No. 45,454  
Attorney for Applicant  
Customer No. 022913  
Telephone No. 801.533.9800